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EXAMINER

TOTH, KAREN E

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/595,917	<b>Applicant(s)</b> BERTHON-JONES ET AL.	
	<b>Examiner</b> KAREN E. TOTH	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-36 and 49-55 is/are pending in the application.
- 4a) Of the above claim(s) 37-48 and 56-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 23-36 and 49-55 is/are rejected.
- 7) ☒ Claim(s) 15-22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/14/10, 8/21/09, 10/17/07, 5/19/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of invention I in the reply filed on 14 May 2010 is acknowledged.
2. Claims 37-48 and 56-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 14 May 2010.

### *Claim Objections*

3. Claims 1-3, 5, 6, 8- 11, 12, 15, 17, 18, 20- 23, 24, 26, and 50 are objected to because of the following informalities:

Claim 1 refers to "the obstruction detection"; there is no antecedent basis for this limitation. For the purposes of examination, the claim will be treated as though reading "sensitivity of detection of the obstruction".

Claim 2 refers to "the size"; there is no antecedent basis for this limitation. For the purposes of examination the claim will be treated as though reading "a size".

Claim 3 refers to "the flow rate"; there is no antecedent basis for this limitation. For the purposes of examination the claim will be treated as though reading "a flow rate".

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Claim 5 refers to "a CPAP apparatus"; this abbreviation has not been defined in the claim. For the purposes of examination the claim will be treated as though reading "a Continuous Positive Airway Pressure (CPAP) apparatus".

Claim 6 refers to "the number"; there is no antecedent basis for this limitation. For the purposes of examination, the claim will be treated as though reading "a number".

Claim 8 refers to "the treatment pressure"; there is no antecedent basis for this limitation. For the purposes of examination the claim will be treated as though reading "a treatment pressure".

Claim 9 refers to "treatment pressure"; there is no antecedent basis for this limitation. For the purposes of examination the claim will be treated as though reading "a treatment pressure".

Claim 10 refers to "treatment pressure"; there is no antecedent basis for this limitation. For the purposes of examination the claim will be treated as though reading "a treatment pressure".

Claim 11 refers to "the threshold"; there is no antecedent basis for this limitation. For the purposes of examination, the claim will be treated as though reading "a threshold".

Claim 12 refers to "the rate at which treatment"; there is no antecedent basis for this limitation. For the purposes of examination the claim will be treated as though reading "a rate at which treatment".

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Claim 15 refers to "the flow rate"; there is no antecedent basis for this limitation. For the purposes of examination the claim will be treated as though reading "a flow rate".

Claim 17 refers to "a CPAP apparatus"; this abbreviation has not been defined in the claim. For the purposes of examination the claim will be treated as though reading "a Continuous Positive Airway Pressure (CPAP) apparatus".

Claim 18 refers to "the number"; there is no antecedent basis for this limitation. For the purposes of examination, the claim will be treated as though reading "a number".

Claim 20 refers to "the treatment pressure"; there is no antecedent basis for this limitation. For the purposes of examination the claim will be treated as though reading "a treatment pressure".

Claim 21 refers to "treatment pressure"; there is no antecedent basis for this limitation. For the purposes of examination the claim will be treated as though reading "a treatment pressure".

Claim 22 refers to "treatment pressure"; there is no antecedent basis for this limitation. For the purposes of examination the claim will be treated as though reading "a treatment pressure".

Claim 23 refers to "the threshold"; there is no antecedent basis for this limitation. For the purposes of examination, the claim will be treated as though reading "a threshold".

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Claim 24 refers to "the rate at which treatment"; there is no antecedent basis for this limitation. For the purposes of examination the claim will be treated as though reading "a rate at which treatment".

Claim 26 refers to "CPAP"; this abbreviation has not been defined in the claim. For the purposes of examination the claim will be treated as though reading "Continuous Positive Airway Pressure (CPAP)".

Claim 50 refers to "CPAP"; this abbreviation has not been defined in the claim. For the purposes of examination the claim will be treated as though reading "Continuous Positive Airway Pressure (CPAP)".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "high" and "low" in claims 1 and 13 are relative terms which render the claims indefinite. The terms "high" and "low" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the

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invention. For the purposes of examination the claims will be treated as though reading "above a particular threshold" and "below a particular threshold".

The examiner notes that claims 11 and 23 refer to a threshold. It is not clear if this threshold is the same as what is used to determine high and low, or if this refers to a different threshold involved in the invention.

6. Regarding claims 29 and 60, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). For the purposes of examination, "appropriate indices such as the" will be treated as though reading "at least one of".

### ***Claim Rejections - 35 USC § 101***

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-12 and 25-36 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. To be statutory, a claimed method must either be tied to a particular machine or apparatus, or transform an article to a different state or thing - that is, it must pass the "machine-or-transformation test". Recitation of a specific machine or particular transformation of a specific article in an insignificant step, such as data gathering or outputting, is not sufficient to pass the test. The claim(s) should positively recite the other statutory class (the thing or product) to which it is tied

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by, for example, explicitly reciting the particular machine or apparatus, or reciting a step that inherently involves the use of a particular machine or apparatus. See *In re Bilski*, 545 F.3e 943, 88 USPQ2d 1385 (Fed. Cir. 2008).

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 2, 11, 13, 14, 23, 25-30, 32-35, and 49-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Stahmann (US 2005/0115561).

Regarding claim 1, Stahmann discloses a method of treating sleep disordered breathing comprising determining an arousal index of a patient for use in an outer loop of a control algorithm, the arousal index being a measure of the frequency of sleep arousals (paragraphs [0502], [0719], [0721], [0736], [0737]), monitoring the patient's respiratory airflow signal in an inner loop of the control algorithm to detect an airway obstruction (paragraphs [0729], [0743], [0744], [0750], [0754]; figure 16E), and if the arousal index is above a particular threshold, increasing the sensitivity of the obstruction detection and/or aggressiveness of a treatment, and if the arousal index is below a particular threshold, decreasing the sensitivity of the obstruction detection and/or the



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aggressiveness of the treatment (paragraphs [0458], [0461], [0727], [0730], [0739], [0745], [0755]).

Regarding claim 2, Stahmann further discloses the arousal index being calculated from the size of the patient's breath (paragraph [0507], since minute ventilation is the product of tidal volume and respiratory rate).

Regarding claim 11, Stahmann further discloses analyzing data with a modified threshold sensitivity in response to detection of an arousal (paragraph [0425], [0600]).

Regarding claim 13, Stahmann discloses an apparatus for treating sleep disordered breathing comprising a controller (paragraph [0498], [0752]) for determining a patient's arousal index for use in an outer loop of a control algorithm, the arousal index being a measure of the frequency of sleep arousals (paragraphs [0502], [0719], [0721], [0736], [0737]), and monitoring the patient's respiratory airflow signal in an inner loop of the control algorithm to detect an airway obstruction (paragraphs [0743], [0744], [00754]), and means responsive to the arousal index being above a particular threshold for increasing the sensitivity of the obstruction detection and/or aggressiveness of a treatment, and responsive to the arousal index being below a particular threshold for decreasing the sensitivity of the obstruction detection and/or the aggressiveness of the treatment (paragraphs [0458], [0727], [0730], [0739], [0745], [0755]).

Regarding claim 14, Stahmann further discloses the arousal index being calculated from the size of the patient's breath (paragraph [0507], since minute ventilation is the product of tidal volume and respiratory rate).

Regarding claim 23, Stahmann further discloses analyzing data with a modified threshold sensitivity in response to detection of an arousal (paragraph [0425], [0600]).

Regarding claim 25, Stahmann discloses a method of monitoring and treating sleep disordered breathing comprising using two control loops, wherein the inner loop is adapted to provide at least two treatment modes and the outer loop is adapted to monitor the effectiveness of therapy provided by the inner loop and control a change in modes if necessary (figure 21; paragraph [0454]).

Regarding claim 26, Stahmann further discloses treatment modes including basic continuous positive airway pressure (CPAP) and bi-level CPAP (paragraph [0202]).

Regarding claim 27, Stahmann further discloses distinguishing between central and obstructive apneas (figure 16E).

Regarding claim 28, Stahmann further discloses the outer loop determining at least two of central apneas, obstructive apneas, hypopneas, and desaturation events (figures 9, 12).

Regarding claim 29, Stahmann further discloses the outer loop determining at least one of an apnea hypopnea index, central apnea index, and desaturation index (paragraphs [0453], [0503]).

Regarding claim 30, Stahmann further discloses the outer loop monitoring the intensity and severity of snoring (element 139; paragraphs [0867]-[0891]).

Regarding claim 32, Stahmann further discloses distinguishing between central and obstructive apneas (figure 16E).

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Regarding claim 33, Stahmann further discloses the outer loop determining at least two of central apneas, obstructive apneas, hypopneas, and desaturation events (figures 9, 12).

Regarding claim 34, Stahmann further discloses the outer loop determining at least one of an apnea hypopnea index, central apnea index, and desaturation index (paragraphs [0453], [0503]).

Regarding claim 35, Stahmann further discloses the outer loop monitoring the intensity and severity of snoring (element 139; paragraphs [0867]-[0891]).

Regarding claim 49, Stahmann discloses an apparatus for monitoring and treating sleep disordered breathing comprising two control loop mechanisms, wherein the inner loop is adapted to provide at least two treatment modes and the outer loop is adapted to monitor the effectiveness of therapy provided by the inner loop and control a change in modes if necessary (figures 1 and 21; paragraph [0454]).

Regarding claim 50, Stahmann further discloses treatment modes including basic continuous positive airway pressure (CPAP) and bi-level CPAP (paragraph [0202]).

Regarding claim 51, Stahmann further discloses the inner loop distinguishing between central and obstructive apneas (figure 16E).

Regarding claim 52, Stahmann further discloses the outer loop determining at least two of central apneas, obstructive apneas, hypopneas, and desaturation events (figures 9, 12).

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Regarding claim 53, Stahmann further discloses the outer loop determining at least one of an apnea hypopnea index, central apnea index, and desaturation index (paragraphs [0453], [0503]).

Regarding claim 54, Stahmann further discloses the outer loop monitoring the intensity and severity of snoring (element 139; paragraphs [0867]-[0891]).

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 12 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann in view of Axe (US 5458137).

Regarding claim 12, Stahmann discloses all the elements of the claimed invention, as described above, except for increasing a rate at which treatment pressure in the inner loop is increased being a function of the aggressiveness of treatment. Axe teaches a method of treating sleep disordered breathing comprising increasing a rate of treatment pressure as a function of the aggressiveness of treatment (column 6, lines 30-37), in order to expedite treatment of the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Stahmann and increased treatment pressure as a function of aggressiveness of treatment, as taught by Axe, in order to expedite treatment of the patient.

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Regarding claim 24, Stahmann discloses all the elements of the claimed invention, as described above, except for the rate at which the controller increases treatment pressure in the inner loop being a function of the aggressiveness of treatment. Axe teaches an apparatus for treating sleep disordered breathing comprising configured to increase a rate of treatment pressure as a function of the aggressiveness of treatment (column 6, lines 30-37), in order to expedite treatment of the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the apparatus of Stahmann and increased treatment pressure as a function of aggressiveness of treatment, as taught by Axe, in order to expedite treatment of the patient.

12. Claims 31, 36, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann in view of Wickham (US 2007/0084464).

Regarding claim 31, Stahmann discloses all the elements of the claimed invention, as described above, except for the outer loop monitoring flow flattening. Wickham teaches a method of monitoring and treating sleep disordered breathing comprising monitoring flow flattening (paragraphs [0002], [0011], [0042]), in order to detect an airway obstruction in the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Stahmann and used the outer loop to monitor flow flattening, as taught by Wickham, in order to detect an airway obstruction in the patient.

Regarding claim 36, Stahmann discloses all the elements of the claimed invention, as described above, except for the outer loop monitoring flow flattening. Wickham teaches a method of monitoring and treating sleep disordered breathing comprising monitoring flow flattening (paragraphs [0002], [0011], [0042]), in order to detect an airway obstruction in the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Stahmann and used the outer loop to monitor flow flattening, as taught by Wickham, in order to detect an airway obstruction in the patient.

Regarding claim 55, Stahmann discloses all the elements of the claimed invention, as described above, except for the outer loop monitoring flow flattening. Wickham teaches an apparatus for monitoring and treating sleep disordered breathing with a mechanism for monitoring flow flattening (paragraphs [0002], [0011], [0042]), in order to detect an airway obstruction in the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Stahmann and used the outer loop to monitor flow flattening, as taught by Wickham, in order to detect an airway obstruction in the patient.

### ***Allowable Subject Matter***

13. The prior art of record fails to anticipate or make obvious the invention of claims 3 and 4, including, *inter-alia*, a method of treating sleep disordered breathing comprising determining if an arousal index is high by monitoring a flow rate over a sequence of

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breaths and determining if the sequence is followed by a large breath, in combination with all other limitations in the claims.

14. The prior art of record fails to anticipate or make obvious the invention of claim 5, including, *inter-alia*, a method of treating sleep disordered breathing comprising using a continuous positive airway pressure apparatus to detect a post apnea sigh or yawn to determine a sleep arousal, in combination with all other limitations in the claim.

15. The prior art of record fails to anticipate or make obvious the invention of claims 6 and 7, including, *inter-alia*, a method of treating sleep disordered breathing comprising detection of airway obstruction using average airflow shape, and increasing sensitivity of detection of obstruction by reducing a number of breaths in the average, in combination with all other limitations in the claims.

16. The prior art of record fails to anticipate or make obvious the invention of claim 8, including, *inter-alia*, a method of treating sleep disordered breathing comprising adjusting a threshold level necessary to increase a treatment pressure in a respiratory airflow monitoring loop is adjusted to change the sensitivity of detection of an obstruction, in combination with all other limitations in the claim.

17. The prior art of record fails to anticipate or make obvious the invention of claim 9, including, *inter-alia*, a method of treating sleep disordered breathing comprising increasing a time constant of decay of treatment pressure in a respiratory airflow monitoring loop in order to increase aggressiveness of treatment, in combination with all other limitations in the claim.

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18. The prior art of record fails to anticipate or make obvious the invention of claim 10, including, *inter-alia*, a method of treating sleep disordered breathing comprising increasing incremental changes in treatment pressure in a respiratory airflow monitoring loop in order to increase aggressiveness of treatment, in combination with all other limitations in the claim.

19. Claims 15-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the invention of claims 15 and 16, including, *inter-alia*, an apparatus for treating sleep disordered breathing comprising a controller that determines if an arousal index is high by monitoring a flow rate over a sequence of breaths and determines if the sequence is followed by a large breath, in combination with all other limitations in the claims.

The prior art of record fails to anticipate or make obvious the invention of claim 17, including, *inter-alia*, an apparatus for treating sleep disordered breathing comprising a controller that uses a continuous positive airway pressure apparatus to detect a post apnea sigh or yawn to determine a sleep arousal, in combination with all other limitations in the claim.

The prior art of record fails to anticipate or make obvious the invention of claims 18 and 19, including, *inter-alia*, an apparatus for treating sleep disordered breathing comprising a controller that detects airway obstruction using average airflow shape, and



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increases sensitivity of detection of obstruction by reducing a number of breaths in the average, in combination with all other limitations in the claims.

The prior art of record fails to anticipate or make obvious the invention of claim 20, including, *inter-alia*, an apparatus for treating sleep disordered breathing comprising a controller that adjusts a threshold level necessary to increase a treatment pressure in a respiratory airflow monitoring loop to change the sensitivity of detection of an obstruction, in combination with all other limitations in the claim.

The prior art of record fails to anticipate or make obvious the invention of claim 21, including, *inter-alia*, an apparatus for treating sleep disordered breathing comprising a controller that increases a time constant of decay of treatment pressure in a respiratory airflow monitoring loop in order to increase aggressiveness of treatment, in combination with all other limitations in the claim.

The prior art of record fails to anticipate or make obvious the invention of claim 22, including, *inter-alia*, an apparatus for treating sleep disordered breathing comprising a controller that increases incremental changes in treatment pressure in a respiratory airflow monitoring loop in order to increase aggressiveness of treatment, in combination with all other limitations in the claim.

### ***Conclusion***

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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US 2010/0076333 to Burton and 2005/0076908 to Lee, which disclose similar inventions.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/  
Primary Examiner, Art Unit 3735

/K. E. T./  
Examiner, Art Unit 3735

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